REMARKS

In response to the Office Action mailed May 1, 2007, Applicant respectfully requests that the Examiner reconsider the above-captioned patent application in view of the following comments. Claims 1-40 remain pending, of which Claims 8-19 and 35 have been withdrawn from consideration. No claims are amended, added or cancelled in this paper.

The results of the Office Action mailed May 1, 2007 are summarized as follows:

CLAIM NOS.	DISPOSITION/REJECTION		
	BASIS	PRIMARY REFERENCE	SECONDARY REFERENCE(S)
1-4, 20-23, 27-29, 31, 33-37, 39	102(b)	DiMatteo US 6,440,164	n/a
1-4, 28, 37	102(e)	Devellian US 2005/0070952	n/a
5, 29, 30, 33-36, 38	103(a)	Devellian US 2005/0070952	Duran US 5,489,297
5, 24, 30, 38	103(a)	DiMatteo US 6,440,164	Duran US 5,489,297
6, 7, 25, 26, 32, 40	103(a)	DiMatteo US 6,440,164	Soetikno US 2002/0143387

DiMatteo Reference - Claim 1

DiMatteo does not disclose or suggest all of the elements recited in Claim 1. For example, DiMatteo does not teach "bio-absorbable means for blocking blood flow past said stent when implanted in a vein" as recited in Claim 1.

DiMatteo teaches a device with two portions: leaf frames and a non-absorbable cell covering that blocks blood flow in one direction in a lumen. The leaf frames may or may not be formed from a bioabsorbable material, and the fact that some embodiments have both non-absorbable leaf frames and a non-absorbable cell covering shows that bioabsorbability is not a central feature of the DiMatteo reference. DiMatteo at 10:51-54. The leaf frames can have apertures that are "covered with cultured tissue cells." DiMatteo at 10:39-40. The end goal is for these cultured tissue cells to remain in place; the cells grow and eventually "provide the fully functioning valve." DiMatteo at 10:49-50. Instead of being bioabsorbed, these tissue cells are designed to remain and to grow, becoming permanent fixtures. Whether or not the leaf frame portion of the DiMatteo device is formed from bioabsorbable material, in every case the cell

covering portion of the DiMatteo device is designed to function as a permanent, non-absorbed valve.

Claim 1 recites, among other things, a "bio-absorbable means for blocking blood flow... ." The portion of the DiMatteo device that may, in some cases, be absorbed by the body cannot, by itself, block blood flow because the "apertures" in the leaf frame allow blood to flow. Moreover, if an absorbable DiMatteo leaf frame were placed in a body without a cell covering, such a device would eventually degrade and disappear, blocking no blood flow. Accordingly, without the cell covering, the DiMatteo technology would fail in its own purpose of providing a replacement vascular valve. DiMatteo therefore teaches that it is the combination of a leaf frame and a cell covering, not either portion taken alone, that can functions as a valve.

DiMatteo therefore fails to teach a "bio-absorbable means for blocking blood flow...." A device that is only partially absorbable is not "bio-absorbable" as the term is understood in the medical device field. The following excerpts from medical literature[1] (full versions of which are included in the appendix) demonstrate use of the term "bioabsorbable" in the art, in a manner consistent with this understanding:

Supporting Quotation	Source
"Unlike a metallic stent, a bioabsorbable stent is designed to be slowly metabolized by the body and completely absorbed over time."	Abbott Announces Positive Six-Month Results From the World's First, Clinical Trial of a Fully Bioabsorbable Drug-Eluting Coronary Stent, Bio-Medicine, Mar. 24, 2007, http://www.bio-medicine.org/medicine-technology/Abbott-Announces-Positive-Six-Month-Results-From-the-Worlds-First-0AClinical-Trial-of-a-Fully-Bioabsorbable-Drug-Eluting-Coronary-Stent-1182-1/.
"Bioabsorbable plates and screws are completely reabsorbed into the body within 12 to 15 months with no sign of being implanted."	William L. Abernathy et al., Nonmetallic Fixation in Elective Maxillofacial Surgery, 71 AORN J. 193, January 2000, http://findarticles.com/p/articles/mi_m0FSL/is_1_71/ai_59035025.

[1] Although three of these articles are dated after the priority date of the present application, they are nonetheless probative of the manner in which the term "bioabsorbable" was used as of the priority date, and confirm the usage evinced by the Abernathy article of January 2000. There is no reason to believe that the usage of the term changed between the priority date and the dates of the later three articles. The agreement between Abernathy and the other three articles indicates that usage remained the same.

Supporting Quotation	Source
"As with all bioabsorbable implants, they biologically resorb over time, allowing the load to transfer to the bone after primary bone healing and eventually completely disappear through safe biological resorbtion."	Inion Ltd., http://www.inion.com/Products/sportmedicine/en_GB/General_FAQ/ (last visited Oct. 29, 2007).
"[B]ioabsorbable stents, once they are bioabsorbed, leave behind only the healed natural vessel."	Ron Waksman, Adjunctive Therapy: Biodegradable Stents: They Do Their Job and Disappear, 18 J. Invasive Cardiology 70, Feb. 2006, http://www.invasivecardiology.com/article/5222#.

These quotations show that the term "bioabsorbable" is used for medical devices that are fully reabsorbed into the body. Thus, where a portion of a device remains or persists on a permanent basis, such as DiMatteo's tissue cells and some embodiments of DiMatteo's leaf frames, the overall device is not bioabsorbable.

For at least the reasons discussed above, the DiMatteo reference does not disclose or suggest the limitations of Claim 1, including the limitation "bio-absorbable means for blocking blood flow past said stent when implanted in a vein."

DiMatteo Reference - Other Claims

Although they recite combinations of features that differ somewhat from that recited in Claim 1, the other independent claims rejected by the Examiner as anticipated by DiMatteo are patentable for the same reasons provided above with respect to Claim 1. For example, independent Claim 20 recites a "bio-absorbable closure device," and Claims 29 and 37 each recite a "bioabsorbable blocking wall." These limitations are not disclosed or suggested by the DiMatteo reference.

Devellian Reference - Claim 1

Devellian does not disclose or suggest all of the elements recited in Claim 1, which stands rejected as anticipated by Devellian. For example, Claim 1 includes the following language: "means for blocking blood flow past said stent when implanted in a vein." This is not taught by Devellian, and in many respects, Devellian teaches away from this element of Claim 1.

The specified limitation of Claim 1 is introduced with the terms "means for." The corresponding function is "blocking blood flow past said stent when implanted in a vein." In the examination of means plus function claims, the Examiner must show that a given prior element performs a function identical to that specified in the claim. See MPEP § 2184, second paragraph; *In re Donaldson*, 16 F.3d 1189 (Fed. Cir. 1994). Moreover, unless an element performs the identical function specified in the claim, it cannot be an equivalent for the purposes of 35 U.S.C. 112, sixth paragraph. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 4 USPQ2d 1737 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 961 (1988). See MPEP § 2184 II, first paragraph. Devellian teaches use of the disclosed device only in the left atrial appendage ("LAA"), not a vein. Thus, the Devellian reference does not anticipate Claim 1, either literally or through an equivalence analysis.

Claim 1 is also patentable over Devellian for reasons of non-obviousness. The Devellian LAA insert device is not suited for positioning in a vein, so a person of ordinary skill in the art would not seek to use the Devellian device in that particular anatomy. Because they are specifically designed for positioning in an LAA, the contours of the Devellian device are not appropriate for any part of the venous system.

The conical/tapering shape and proximal flange of the Devellian device make it ill suited for positioning in a vein lumen. If the Devellian device were so positioned, the rim of the flange (and likely no other portion of the device) would abut the vein wall, causing high pressure concentration and possible injury of the vein wall or surrounding tissue in the small abutting rim region. Alternatively, the device would slip and migrate within the vein due to insufficient engagement of the device to the vein wall. Blood flow would also be problematic – if the device tip is pointed "into" the oncoming blood flow, the taper/cone would force the blood flow outward against the vein wall, tending to dilate the vein and lead to dislodgement and migration of the device. Because blood tends to flow in both directions in a vein afflicted by venous reflux disease, this vein dilation effect would inevitably occur in a class of patients who can benefit greatly from vein occlusion.

If positioned in a vein ostium (i.e. with the cone/taper projecting into the "branch" vein lumen and the flange abutting the wall of the "main" vein at the junction), the Devellian device would be quickly ejected from the ostium by blood flow, as the physiological blood flow in the

venous system proceeds from smaller branch veins into larger main veins. (Again, bi-directional blood flow would be observed in refluxing veins, with the same result.)

For at least these reasons, there is little reason to expect that one could successfully position the Devellian device in a vein, and therefore one of ordinary skill in the art would not attempt to do so.

Devellian Reference - Claims 37 and 29

The Examiner rejected Claim 37, alleging it was anticipated by the Devellian reference. The Examiner also rejected Claim 29, alleging obviousness in light of the Devellian and Duran references. These rejections are incorrect for at least the reason that Claim 37 recites a "side wall being substantially conformable to a vein wall," and Claim 29 recites "a non-filtering, continuous side wall defining the lumen of the body and substantially conformable to the wall of the vein...." These rejections are incorrect because the Devellian cone cannot conform to the more-or-less cylindrical shape of a vein lumen, or to any portion of a vein that does not taper at precisely the same angle as the cone.

Moreover, Devellian's own disclosure lacks any teaching of conformance to the LAA. As seen in Fig. 4, there is only intermittent contact between the device 30 and the LAA – indeed, from inspection of Fig. 4, fully 4/5, or 80%, of the length of the device 30 has no contact with the LAA. Likewise, in Fig. 2B, the liner 21 is depicted as being out of contact with the LAA along most of its length.

Devellian's device would have even less contact in a vein. At most, the flange and a small portion of the cone/taper would abut the vein wall, with the bulk of the device out of contact with the vein.

In addition, one skilled in the art would not seek to turn the Devellian device into one that would have a "side wall being substantially conformable to a vein wall" as recited by Claim 37 or "a non-filtering, continuous side wall defining the lumen of the body and substantially conformable to the wall of the vein..." as recited in Claim 29. Devellian's liner and anchor are shaped in the disclosed tapered, conical manner to achieve Devellian's emphatically stated purposes of remodeling and decreasing the volume of the LAA (See Devellian, ABSTRACT, paragraphs [0011], [0027]). If the Devellian device did in fact conform to the LAA there would be little decrease in volume of the LAA, defeating these important purposes. The flange is also

critical for the proper functioning of the Devellian device. Whether implemented as a small flange as in Figure 2B or a more pronounced flange as in Figure 4, the flange is necessary to prevent the device from falling into the LAA. To modify the Devellian device to make it conformable to the LAA or to a vein wall (such as by changing its shape or removing the flange) would defeat the purposes emphasized by Devellian. Therefore such modifications of Devellian cannot be considered obvious. See M.P.E.P. § 2143.01 V, emphasizing that a proposed modification cannot render the prior art unsatisfactory for its intended purpose.

In view of the foregoing, Applicants respectfully submit that the rejections of Claims 37 and 29 over Devellian should be reconsidered and withdrawn. As to Claim 37, Devellian does not teach or suggest all of the recited limitations and Devellian therefore does not anticipate the claim. Claim 29, rejected as obvious over Devellian in view of Duran, is believed to be allowable as the cited references, even if combined, do not collectively teach or suggest all of the claimed limitations.

Dependent Claims

Numerous dependent claims remain pending but rejected over the prior art. Applicant respectfully submits that the pending dependent claims are also in condition for allowance, due to their dependence from allowable based claims as well as their recitation of further novel and non-obvious combinations of features.

Conclusion

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although the present communication may include alterations to the claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including any subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history should not infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application. Moreover, any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, David G. Jankowski, at (949) 721-6334 to resolve such issue(s) promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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